UKBTS/NIBSC
STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS
SNBTS PFC EDINBURGH

10 SEPTEMBER 1998, 11.00 AM

MINUTE

SACBC 98.4 1.1 **PRESENT**

Dr L Williamson (Chair)	**LW**
Mr M Bruce (Secretary)	**MB**
Dr C Dash	**CD**
Mr P Garwood	**PG**
Dr D Pamphilon	**DP**
Dr CV Prowse	**CVP**
Mr A Slopecki	**AS**

SACBC 98.4 1.2 **APOLOGIES**

Apologies were received from Mrs M Ashford; Dr K Forman and Dr P Metcalfe.

SACBC 98.4 1.3 **MINUTES OF 12 JUNE 1998 MEETING**

1.3.1 One minor amendment was noted:
i) SACBC 98.3 4. The Draft document under consideration was the 5th Draft, not the 4th as stated in the minute.

1.3.2 With this minor amendment, the minutes were approved as a true record.

SACBC 98.4 2. **MINUTES OF RED BOOK EXECUTIVE MEETING 15 JUNE 1998**

SACBC 98.4 2.1 DISTRIBUTION OF SACBC MINUTES

MB agreed to send copies of approved minutes of SACBC to the Chair of the Executive Committee, the four National Medical Directors and each SAC Chair. LW to provide a mailing list for SAC Chairs. **MB** **LW**

SACBC 98.4 2.2 LW referred to p2 item 4 of the Executive Committee minute and advised that once appointed, the incoming Chair will be invited to draw up proposals for the constitution of SACs, including terms of office for all members.

SACBC 98.4 2.3 Re page 5 item 9, the Executive acknowledged the efforts of SACBC in providing a comprehensive list of comments to the Draft 5th Edition of the Council of Europe text.

SACBC 98.4 2.4 Re page 8/9 Generic Evaluation Protocols. All generic protocols were approved by the Executive, subject to any minor amendments raised by SACBC (at 10 September 1998 meeting). See 3.2 .

SACBC 98.4 2.5 Re page 9 - items on FFP, Methylene Blue Treated and Components suitable for IUT, neonates and infants under 1 year. See 3.3; 3.4; 3.5.

SACBC 98.4 3. **MATTERS ARISING**

SACBC 98.4 3.1 USE OF TPO

At the last SACBC meeting, DP had summarised the work of the sub-group that was considering growth factors. This group had agreed that they could not support the use of TPO in volunteer donors (SACBC 98.3 2.2.3 Page 2).

LW tabled a paper (L151) from SCRIP (2363, 21 August 1998 page 16) which reported that Amgen had withdrawn from their trial of TPO use in platelet donors and patients due to development of platelet antibodies.

LW agreed to write to the 4 National Medical Directors to advise them of SACBC's view that TPO should not be used in donors. LW

SACBC 98.4 3.2 PROTOCOLS FOR COMPONENT EVALUATION

3.2.1 Various changes were agreed for these protocols. SACBC accepted that once these amendments had been made, the documents should be released for printing and issue. Specific actions on the various protocols are listed below.

3.2.2 L129 - was approved without change. LW to e-mail to MB. LW

3.2.3 L149 - some minor amendments to be made by MB. It was agreed that this document should, in the first instance, be used to evaluate packs for routine whole blood collection. MB

LW would send a copy of the revised document to Moje Gesinde for comment. LW

3.2.4 L130 - various amendments were made, LW to e-mail to MB who will make the amendments and confirm these with DP. LW/MB DP

3.2.5 L131 - various amendments were agreed. LW to e-mail the document to MB who will action these and confirm them with CVP. LW MB CVP

3.2.6 L132 - various amendments were agreed. LW to e-mail the document to MB who will make the changes and confirm them with LW. LW MB

3.2.7 MB to e-mail final, revised versions to WW. Target date - end of September 1998. MB

SACBC 98.4 3.3 REVISION OF SPECIFICATIONS OF COMPONENTS SUITABLE FOR IUT, NEONATES AND INFANTS UNDER 1 YEAR

3.3.1 Following the last SACBC meeting (12 June 1998), MB had

actioned various agreed changes; the Red Book Executive Committee proposed further changes on 15 June 1998. LW had issued L 133 as a final revision. A number of further changes were agreed by SACBC. Significant points are noted below:

3.3.2 There were various inconsistencies across the document - eg with respect to CMV negative; labelling requirements; etc.
MB agreed to edit these to achieve a consistent approach to neonatal components. MB

3.3.3 It was agreed that clarification should be given to various time limits - ie it was accepted that specifying time from venepuncture was optimal but that the convention of days from midnight day 0 was, at present, more realistic.

3.3.4 It was agreed that white cell counts should be defined as follows:
i) Red cell and plasma components - < $5x10^6$ / starting donation.
ii) Platelets - < $5x10^6$ / starting donation.
iii) Platelets for IUT < $2.5x10^6$ / donation.

3.3.5 It was noted that a specification for Whole Blood for Exchange had been introduced at the request of the Executive Committee. As SACBC had agreed on 22 April 1998 that this component should not be included, it was agreed that demand (for this component) should be monitored over the next year. MB to keep on agenda. MB

3.3.6 It was noted that the Executive had accepted the view from SACTTI that there was insufficient evidence to support equivalence between leucodepletion and CMV seronegativity. This would be reflected in the 'neonatal' component specifications. SACBC agreed it would be inappropriate to change any other blood component specifications at this time.

3.3.7 There was discussion about the reference to screening for HbS donors - ie was not specified for all neonatal red cell components. SACBC agreed that, if required, screening should be required by all Centres and for all neonatal red cell components. LW would seek the view of BCSH Blood Transfusion Task Force regarding the necessity for screening. LW

3.3.8 LW agreed to e-mail L133 to MB who would make the necessary changes. LW
Any remaining issues to be sent to MB before 17 September 1998. MB

SACBC 98.4 3.4 METHYLENE BLUE FFP

3.4.1 SACBC noted the decision of the Executive Committee not to approve the draft component specification at this time and that of the NBA to implement MBT plasma along with leucodepletion. SNBTS have been issuing MBT for some months.

3.4.2 With reference to L134 and L135, SACBC considered that commenting on toxicological safety of MBT FFP was a regulatory matter that was outwith the SAC's remit.

3.4.3 The SACBC also considered L145 - L148 and discussed the use of non-pharmaceutical grade (ie - chemical grade) Methylene Blue (MB) by Baxter, Griffols and Springe. There is no monograph for MB for injection in the European Pharmacopoeia. However, there is a monograph in the US Pharmacopoeia and Baxter had used this as their QC specification for methylene blue. CVP/CD advised this is standard practice in the Pharmaceutical Industry.

3.4.4 SACBC understood that further information was awaited from Baxter, but were concerned to note that as a consequence of the response from Merck (L146), the Irish Blood Transfusion Service Board (L145) had abandoned their MBT plasma project for the time being and were investigating the use of quarantined plasma instead.

3.4.5 In view of 3.4.4, and since SNBTS were currently providing MBT FFP, MB would write to MCA to seek their view on the matter; LW would write to Baxter and Griffols for their CE marking certificate for MBT. MB LW

SACBC 98.4 3.5 LEUCOCYTE DEPLETION AND CMV SAFETY

3.5.1 SACBC discussed the various documents (L136 - L139; L143; L152; L153 - the latter two documents were tabled at the meeting).

3.5.2 Consensus seemed to be leaning towards leucodepleted components being at least as safe for CMV as seronegatives. SACBC agreed that the best way to approach this matter was to organise a joint meeting with SACTTI (see SACBC 98.4 6).

SACBC 98.4 3.6 LEUCODEPLETION AND PROCESSING TEMPERATURE

Re: SACBC 98.3 2.7.(p4). It was felt that more specific direction was needed to indicate how this would be taken forward. LW advised that Birmingham blood centre were planning to move to 100% leucodepletion in the near future. They would be studying temperature rise in a typical batch of blood removed from 4^{0}C for processing at room temperature. MB to keep on the agenda.

MB

SACBC 98.4 4. **EVALUATION OF COBE TRIMA**

SACBC 98.4 4.1 Re L125 - L127, SACBC endorsed the views expressed by LW and Moje Gesinde regarding COBE's unofficial and premature announcement of approval.

SACBC 98.4 4.2 Re L140, SACBC considered the Technical Report of Phase 1 evaluation and agreed the following:

4.2.1 LW will write to Moje Gesinde indicating that SACBC approve in principle to the progression of the trial to phase 2, pending the receipt of the following information: LW

- the calculation for haemolysis shown as a percentage;
- if historical data were used to provide control information, this

should be shown. If no controls (historical or otherwise) were used the data would be invalid;

- the values for white cell counts show zeros. Where this reflects a count below the limit of detectability this should be shown and the limit shown in a footnote.

4.2.2 Other points to be covered in this correspondence would be whether the Trima is fitted with a haemolysis detector/alarm system; the apparent incidence of reactions to citrate reported in L128 and the availability of a barcode for red cells in additive solution. (The eye-readable content to be equivalent to red cells in additive solution, the barcode to be different - Mike Clarke at Leeds RTC will advise).

SACBC 98.4 5. **PRODUCTION OF DONOR LYMPHOCYTE COLLECTIONS**

SACBC discussed L141 and concluded that in the longer term this may be more appropriately dealt with by the SACTB sub-group on stem cells. It was felt that issue of a bar code would be difficult at this stage as the component would be donor'/patient specific and vary in dose, precluding issue of a standard specification. LW to advise Dr Napier accordingly. LW

SACBC 98.4 6. **PLANNING FOR QUALITY REVIEW**

6.1 It was agreed that the meeting on 04 November 1998 be cancelled in favour of an extended meeting with SACTTI on 17 December 1998 at NBA, Watford. This would primarily address quality aspects of leucodepletion including: process control; sampling protocols; counting technology; proficiency scheme plans; performance data to date; implementation plans.

6.2 Re CMV safety and leucodepletion:

6.2.1 SACTTI (P Flanagan) had advised LW they would make contact with transplant groups to establish which data were available. LW would enquire if a response had been received. LW

6.2.2 DP has some data which he will collate and will pursue this via BSBMT (Mike Potter). LW

6.2.3 CVP suggested contacting a statistician to approach the subject from the opposite direction - ie from available literature, what is the projected white cell limit that would equate to CMV safety - ie may be less stringent than $5x10^6$. CVP to pursue. CVP

6.2.4 LW would attempt to obtain a copy of the FDA Memorandum on CMV seronegative: leucodepletion equivalence at the forthcoming BPAC meeting. LW

SACBC 98.4 6.3 DP offered to produce an outline agenda for the 17 December meeting with proposed contributors, and will circulate to SACBC for comment by end September 1998.

SACBC 98.4 7. **DATE, TIME AND VENUE OF FUTURE MEETINGS**

17 December 1998, NBS Watford